

Remarks

Claims 10, 13, 16 and 33 are amended. No new matter was added by way of these amendments. Claims 4, 11, 14 and 19-32 are cancelled. Claims 1-3, 5-10, 12-13, 15-18 and 33-34 are pending in this application.

The 35 U.S.C. § 103(a) Rejections

The Examiner has rejected claims 1-3, 5-6, 9, 12, 15 and 17-18 under 35 U.S.C. § 103(a) as being unpatentable over Takayanagi et al. (Takahanagi) in view of Ventouras et al. (Ventouras). This rejection is respectfully traversed.

Applicants' rejected claims recite a pharmaceutical carrier device comprising a layered flexible film having a first water-erodable adhesive layer and a second, water-erodable non-adhesive backing layer. The first layer comprises a film-forming polymer and a bioadhesive polymer and is free of plasticizer. The second layer comprises hydroxyethyl cellulose.

The Examiner asserts that the combination of Takayanagi and Ventouras discloses Applicants' claimed invention because Takayanagi allegedly discloses a two layer adhesive medical tape having an adhesive medicament-containing layer and a support layer containing hydroxypropyl cellulose and Ventouras allegedly discloses the equivalence of hydroxypropyl cellulose and hydroxyethyl cellulose as swellable polymers.

First of all, Applicants submit that the Examiner has misquoted Ventouras. Ventouras does not disclose the equivalence of hydroxypropyl cellulose and hydroxyethyl cellulose. The Examiner points to col. 1, lines 48-52 as the passage disclosing this alleged equivalence. However, this passage recites a water-insoluble polymeric substance such as hydroxypropyl **methyl**cellulose, hydroxyethyl cellulose, hydroxymethyl cellulose, carboxymethylcellulose, sodium carboxymethylcellulose, alginic acid and crystalline cellulose. The Examiner has mistaken the compound "hydroxypropyl **methyl**cellulose" for the compound "hydroxypropyl cellulose".

This mistaken identity is consequential. Hydroxypropyl methylcellulose and hydroxypropyl cellulose are very different materials. Hydroxypropyl methylcellulose is swellable but not soluble in water and is insoluble in alcohol or chloroform. Hydroxypropyl cellulose, however, is soluble in water, alcohol and organic solvents such as chloroform. See the

attached page 626 of "Hawley's Condensed Chemical Dictionary", Sax and Lewis, Ed's., Van Nostrand Reinhold, New York, N.Y., 1987. Hence, hydroxypropyl cellulose is not a swellable polymer as asserted by the Examiner.

Second, the Examiner has also misquoted Takayanagi. The Examiner points to Takayanagi at col. 3, lines 61-64 as disclosing Takayanagi's hydroxypropyl cellulose. This passage discloses no such information. Instead, it is believed that the Examiner meant to refer to the passage at col. 3, lines 3-5, which recites "a water-swellaible polymer such as lowly substituted hydroxypropyl cellulose". Alternatively, the Examiner may have meant the passage col. 2, lines 66-67, which recites "hydroxy-propyl cellulose [in particular a highly substituted one]".

Both of these Takayanagi recitations refer to the polymer in the medicament or adhesive layer, not the support layer of Takayanagi's tape. Takayanagi discloses a tape formed of two layers: a medicament-containing layer and a support layer. Takayanagi also calls his support layer an intestine-soluble layer. See col. 2, lines 7-12. Takayanagi's medicament layer is his adhesive layer while his support layer is non-adhesive. See col. 3, lines 50-60.

The reason why this detail about the layers is important lies in the Examiner's assertion of equivalence. The Examiner states that the hydroxypropyl cellulose of Takayangi is equivalent to hydroxyethyl cellulose because of Ventouri. Notwithstanding the mistake on which the alleged Ventouri equivalence is based, that statement puts the hydroxyethyl cellulose of Ventouri into the wrong layer. It puts the hydroxyethyl cellulose into the adhesive layer of Takayanagi, and not into the non-adhesive backing layer as Applicants' claims require. Thus, this art does not provide a disclosure of hydroxyethyl cellulose as a component of a non-adhesive backing layer as is required by Applicants' claims. Hence, Takayangi and Ventouras do not lead to Applicants' claimed invention even if one were motivated to make this combination.

That motivation is lacking also. Applicants respectfully submit that one skilled in the art would not have been motivated to combine the disclosures of Takayanagi and Ventouras. Takayanagi disclose an adhesive medical tape, while Ventouras discloses a tablet. Applicants respectfully submit that one skilled in the art would not look to art related to tablets to modify the backing layer (i.e., support layer) of an adhesive medical tape. Takayanagi's tape is designed to adhere to mucous surfaces. Ventouras tablet is designed to be swallowed, i.e., not adhere to

mucous surfaces. Takayanagi's tape has the medicament in a layer on one side and a backing on the other. Ventouras' tablet has a core containing the medicament. His core is completely surrounded by an elastic, water insoluble coating such that it has no ability to adhere. Takayanagi's tape delivers medicament to the oral cavity which Ventouras' tablet does not release medicament until it is in the intestine. Thus, there would have been no motivation to combine the cited documents.

In light of the above remarks, it is respectfully submitted that the claimed invention is patentable over Takayanagi et al. in view of Ventouras. The Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1-3, 5-6, 9, 12, 15 and 17-18 under 35 U.S.C. § 103(a).

The Examiner also rejected claims 1-3, 5-9, 12, 15, 17-19 and 34 under 35 U.S.C. § 103(a) "as being unpatentable over Takayanagi et al in view of Ventouras as applied to claim WO 95/05416 (WO '416) and EPA 250187 (EPA '187) above, and further in view of Takayanagi et al In view of Ventouras is discussed above." This rejection is respectfully traversed.

Applicants respectfully submit that the rejection, as quoted above, is confusing. Applicants do not understand how these documents are being combined or applied. If the Examiner maintains this rejection, Applicants respectfully request clarification in a second, non-final Office Action. Additionally, claim 19 was previously canceled, and thus, Applicants believe that claim 19 was included in the rejection in error. If this is incorrect, correction by the Examiner is requested in the next Official Communication.

Although Applicants do not understand this rejection, they respond that the combination of Takayanagi and Ventouras does not suggest their claimed invention as they have explained in the foregoing discussion. Applicants reserve the right to comment and distinguish the additional references once their applicability is explained.

In light of the above remarks, it is respectfully submitted that Applicants' pending claims 1-3, 5-9, 12, 15, 17-18 and 34 are patentable over Takayanagi et al., Ventouras, WO '419, and EPA '187. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-3, 5-9, 12, 15, 17-18 and 34 under 35 U.S.C. § 103(a).

Allowable Subject Matter

The Examiner objected to claims 10, 13, 16 and 33 as being dependent on a rejected base claim, but indicated that claims 10, 13, 16 and 33 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 10, 13, 16 and 33 have been rewritten in independent form.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (612) 373-6939 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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June 22, 2004

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*Hawley's
Condensed Chemical
Dictionary*

ELEVENTH EDITION

Revised by

N. Irving Sax

and

Richard J. Lewis, Sr.



VAN NOSTRAND REINHOLD COMPANY
New York

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2-HYDROXYPROPYLAMINE

626

monomer used in manufacture of thermosetting acrylic resins for surface coatings.

Properties: A liquid with mw 130.14, bp 77C at 5 torr.

Hazard: TLV: 0.5 ppm in air. Corrosive to skin and eyes. Toxic by skin absorption.

Use: In manufacture of thermosetting resins for surface coatings.

2-hydroxypropylamine. See isopropanolamine.

hydroxypropyl cellulose. CAS: 9004-64-2.

A cellulose ether with hydroxypropyl substitution.

Properties: White powder; soluble in water, methyl and ethyl alcohols, and other organic solvents. Thermoplastic; can be extruded and molded. Insoluble in water above 37.7C. Combustible.

Grade: FCC.

Use: Emulsifier, film former, protective colloid, stabilizer, suspending agent, thickener, food additive.

hydroxypropylglycerin.

Properties: Pale straw-colored liquid, d 1.084 (25/25C), refr index 1.459 (25C), flash p 380F (193C), pour p -23C, soluble in water and methanol. Combustible.

Use: Intermediate for alkyd resins and polyesters, plasticizer for cellulose, glue, starch, etc.

hydroxypropyl methacrylate.

$\text{CH}_3\text{CHOHCH}_2\text{OOCCH}(\text{CH}_3)\text{CH}_2$.

Properties: Clear, mobile liquid. D 1.066 (25/16C), refr index 1.446 (25C), flash p 206F (96.6C), limited solubility in water, soluble in common organic solvents. Combustible.

Use: Monomer for acrylic resins, nonwoven fabric binders, detergent lube oil additives.

hydroxypropyl methylcellulose. (methylcellulose; propylene glycol ether).

Properties: White powder, swells in water producing clear to opalescent, viscous, colloidal solution; insoluble in anhydrous alcohol, ether, and chloroform. Combustible.

Grade: NF, FCC.

Use: Food products (except confectionery), as thickening agent, stabilizer, emulsifier; thickener in paint-stripping preparations.

N-β-hydroxypropyl-o-toluidine.

$\text{CH}_3\text{C}_6\text{H}_4\text{NHCH}_2\text{CH}(\text{OH})\text{CH}_3$.

Properties: Amber color, distillation range 170-180C (20 mm), d 1.035-1.045 (20/20C), refr index 1.540-1.550 (20C).

Use: Dye intermediate.

4-hydroxy-2H-pyran-3,3,5,5(4H,6H)tetramethanol. See anhydroenneaheptitol.

2-hydroxypyridine-N-oxide. Bactericidal agent related to aspergill acid, made from pyridine-N-oxide.

1-hydroxy-2-pyridine thione. (2-pyridinethiol-1-oxide). $\text{C}_5\text{H}_4\text{NOH}(\text{S})$. Apparently exists in equilibrium with the -SH form. Forms chelates with iron, manganese, zinc, etc.

Use: fungicide, bactericide.

4-hydroxy-2-pyrrolidinecarboxylic acid. See hydroxyproline.

8-hydroxyquinoline. (8-quinolinol; oxyquinoline; oxine). CAS: 148-24-3. $\text{C}_9\text{H}_6\text{NOH}$.

Properties: White crystals or powder, darkens when exposed to light, technical grade usually tan; almost insoluble in water; soluble in alcohol, acetone, chloroform, benzene, also in formic, acetic hydrochloric, and sulfuric acids and in alkalies; phenolic odor; mp 73-75C; bp 267C.

Grade: CP, technical.

Hazard: Toxic by ingestion.

Use: Precipitating and separating metals, preparation of fungicides, chelating agent, disinfectant.

8-hydroxyquinoline benzoate. CAS: 86-75-9.

$\text{C}_9\text{H}_6\text{NOH} \cdot \text{C}_6\text{H}_5\text{COOH}$.

Properties: Yellowish-white crystals with a saffron odor, mp 56-61C, almost insoluble in water, soluble in alcohol and glycerol.

Use: Antiseptics, fungicide, recommended against Dutch elm disease.

8-hydroxyquinoline sulfate. CAS: 134-31-6.

$(\text{C}_9\text{H}_7\text{NO})_2 \cdot \text{H}_2\text{SO}_4$.

Properties: Pale yellow powder, slight saffron odor, burning taste, melting range 167-182C, soluble in water, slightly soluble in alcohol, insoluble in ether.

Use: Antiseptic, antiperspirant, deodorant, fungicide.

4-hydroxysalicylic acid. See β-resorcylic acid.

12-hydroxystearic acid. CAS: 106-14-9.

$\text{CH}_3(\text{CH}_2)_5(\text{CHOH})(\text{CH}_2)_{10}\text{COOH}$.

A C_{18} straight chain fatty acid with an -OH group attached to the carbon chain, mp 79-82C. It is produced by hydrogenation of ricinoleic acid. Combustible.

Use: Lithium greases, chemical intermediates.

1,12-hydroxystearyl alcohol. (1,12-octadecanediol). A long-chain fatty alcohol made by re-

duction of the -COOH group.

Properties: Use: Chemical synthesis agents, plasticizers.

hydroxysuccinic acid.

α-hydroxytoluene.

hydroxytoluene.

hydroxytoluene.

1-hydroxytoluene.

5-hydroxytoluene.

4-hydroxytoluene. See γ-undecylenol.

hydrozincite. A natural mineral. Properties: Dull to silvery, hardness 3-4. Occurrence: In the form of a mineral. Use: As a source of zinc.

hydrene. 1-methylhydrene. Use: High purity hydrocarbon.

"Hyfac."²⁴ fatty acid esters.

"Hyform." paraffin. Use: Binding agent for die casting.

"Hygromi" and food.

hygromycin. Properties: Soluble in water. Use: Medication.

hygroscopic. the property of absorbing moisture.